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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/920,286	08/02/2001	Xiaobin Zhao	09736-264001	3882
26191 7590 07/12/2007 FISH & RICHARDSON P.C. PO BOX 1022 MINNEAPOLIS, MN 55440-1022			EXAMINER LEWIS, PATRICK T	
			ART UNIT 1623	PAPER NUMBER
			MAIL DATE 07/12/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/920,286

Applicant(s)

ZHAO, XIAOBIN

Examiner

Patrick T. Lewis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8 and 37-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8 and 37-42 is/are allowed.
- 6) ☒ Claim(s) 43-46, 48 and 49 is/are rejected.
- 7) ☒ Claim(s) 47 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☒ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 27, 2007 has been entered.

Applicant's Response Dated April 27, 2007

2. Claims 8 and 37-49 are pending. An action on the merits of claims 8 and 37-49 is contained herein below.

3. The rejection of claims 43-45 and 48-49 under 35 U.S.C. 102(b) as being anticipated by Malson US 4,963,666 (Malson) is maintained for the reasons of record as set forth in the Office action mailed on February 26, 2007.

4. The rejection of claims Claim 46 under 35 U.S.C. 103(a) as being unpatentable over Malson US 4,963,666 (Malson) is maintained for the reasons of record as set forth in the Office action mailed on February 26, 2007.

Rejections of Record Set Forth in the Office Action Dated February 26, 2007

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
6. Claims 43-45 and 48-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Malson US 4,963,666 (Malson).

Malson teaches that a method commonly employed for producing insoluble polymeric materials involves covalent crosslinking of soluble polymers with bifunctional or polyfunctional reagents (columns 1-3). Crosslinking of polysaccharides is often performed by reacting the hydroxyl groups of the polysaccharides in an alkaline aqueous solution with bi- or polyfunctional epoxides to thus bind the polysaccharide chains to one another via ether bonds, with concomitant formation of a gel. A process for producing degradable polysaccharide gels is described in Swedish patent application 8403817-3 according to which carboxyl groups of the polysaccharides are crosslinked with di- or polyfunctional epoxides by means of acid catalysis, whereby an insoluble gel is formed. In this case the bonds produced are ester bonds which in contrast to ether bonds are degradable in physiological environments. Malson teaches a method for producing gels of crosslinked polysaccharides by which it becomes possible inter alia to combine the aforesaid methods for acid- and base-catalyzed crosslinking so as to produce novel gel materials of controllable degradability. The principle of the manufacturing process is as follows: the polysaccharide containing carboxyl groups is at first reacted with a bi- or polyfunctional epoxide. This reaction may be performed in an alkaline, acidic or neutral medium. Following the removal of

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excess epoxide, the polysaccharide is dried at a desired pH. In the course of the drying process the polysaccharide molecules which have been epoxy-activated in the preceding step will move into closer proximity to each other and will become crosslinked. The process is particularly useful for producing water-sellable films of hyaluronic acid. Conditions in which the initial epoxy-activation takes place may be varied within a wide range and are chosen according to the properties desired in the final product. As has been mentioned above ester bonds are obtained under acidic reaction conditions. Where it is desired to introduce this type of degradable bonds in the first step a pH is chosen within the range of from 2 to 6. By contrast, stable ether bonds are obtained if the activation is carried out at a pH ≥ 8 . At a neutral pH a mixture of the two types of bonds will be obtained. An example of a product according to the invention is the material obtained if the initial activation is carried out with a bi- or polyfunctional epoxide in an alkaline medium and the final crosslinking is carried out in an acidic medium after removal of non-bound reagent. Alternatively, the activation may be performed in an acidic medium and the final crosslinking in an alkaline medium; the thus resultant product is another example of a product according to the invention. It will be appreciated that in both cases the final product will contain both ester bonds and ether bonds.

7. Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Malson US 4,963,666 (Malson) as applied to claims 43-45 and 48-49 above.

Malson differs from the instantly claimed invention in that Malson does not explicitly teach the use of 1,2,3,4-diepoxbutane or 1,2,7,8-diepoxyoctane; however, the

use of known members of classes of reagents in reactions to effectuate the same type of modifications taught in the prior art is not seen to render the instantly claimed methods obvious over the art. Once the general reaction has been shown to be old, the burden is on the applicant to present reason or authority for believing that a group on the starting compound would take part in or affect the basic reaction and thus alter the nature of the product or the operability of the process and thus the unobviousness of the method of producing it.

8. Applicant's arguments filed April 27, 2007 have been fully considered but they are not persuasive. Applicants argue that Malson does not teach or suggest a method that includes contacting crosslinked HA with a further amount of the crosslinking agent or with a second crosslinking agent as to form a second type of functional bond. The examiner respectfully disagrees with applicant's characterization of Malson. Applicant's attention is directed to column 2, lines 8-25, wherein Malson sets forth the principles of the manufacturing process. The bi- or polyfunctional epoxide serves as the initial crosslinking agent and forms either an ether or ester bond with the polysaccharide. This initial step meets the instant limitation of "contacting said HA with a first crosslinking agent so as to form a first type of functional bond." Malson teaches, "Conditions in which the initial epoxy-activation takes place may be varied within a wide range and are chosen according to the properties desired in the final product. An important point is that gel formation has to be avoided in this initial step." See column 2, lines 49-57. The epoxy-activated polysaccharide serves as a second crosslinking agent and forms either an ether or ester bond with a second polysaccharide in close proximity. In

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column 3, lines 24-28, Malson teaches, "The crosslinking reaction which constitutes the final step is carried out in that after adjustment to a suitable pH (which as has been explained above implies selection of the bond type) the solution is dried so as to give a product in the desired shape." The final step of Malson meets the instant limitation of "contacting said HA with a further amount of said cross-linking agent or with a second cross-linking agent so as to form a second type of functional bond."

Conclusion

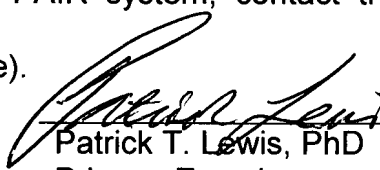
9. Claims 8 and 37-49 are pending. Claims 43-46 and 48-49 are rejected. Claim 47 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 8 and 37-42 are allowed.

Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 571-272-0655. The examiner can normally be reached on Monday - Friday 10 am to 3 pm (Maxi Flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Patrick T. Lewis, PhD
Primary Examiner
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